# Disparities in initiation of combination antiretroviral treatment and in virologic suppression among patients in the HIV Outpatient Study (HOPS), 2000-2013

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The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention (CDC).

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ABSTRACT

*Objectives:* The National HIV/AIDS Strategy emphasizes virologic suppression to reduce HIV incidence in the United States. We assessed temporal trends of and disparities in time to combination antiretroviral therapy (cART) initiation and HIV virologic suppression (VS) in a large, demographically diverse cohort of HIV-infected patients.

*Design:* We included antiretroviral-naïve HIV Outpatient Study (HOPS) participants from 2000-2013 enrolled within six months of their HIV diagnosis who attended ≥ 2 HIV care-related visits.

*Methods:* We evaluated time from HIV diagnosis to first use of cART, time from HIV diagnosis to VS and time from first use of cART to VS. Kaplan-Meier time-to-event curves and Cox proportional hazards models were used to assess temporal trends and correlates of initiating cART and achieving HIV VS (<500 copies/mL).

*Results:* Among 1,156 HOPS patients (median age, 37 years; 43.2% non-Hispanic/Latino black [NHB], 14.1% Hispanic/Latino), estimated median times from HIV diagnosis to cART initiation, and from HIV diagnosis to VS, both shortened by > 40% during the 13.5-year study period, reaching, respectively, 2.5 and 5.4 months. In multivariable analyses, NHB patients (as compared with non-Hispanic/Latino white) and those who had injected drugs (as compared with those who did not) initiated cART in a less timely fashion. After adjusting for CD4+ cell count and viral load at cART initiation, NHB patients and those aged < 30 years (compared with ≥ 40 years) had lower rates of VS.

*Conclusions:* Despite improvements in HIV treatment over time, patients who were NHB, younger, or used injection drugs had less favorable outcomes.

## INTRODUCTION

The National HIV/AIDS Strategy in the United States (US) emphasizes the importance of virologic suppression to improve the health of HIV-infected individuals and to reduce population-level transmission of HIV infection [1]. Modern combination antiretroviral therapy (cART) regimens are better tolerated and less complex than older regimens, increasing the likelihood of achieving virologic suppression. The success of HPTN 052, the HIV Prevention Trials Network randomized trial which demonstrated 96% reduction in HIV transmission with use of cART in HIV serodiscordant couples, lent support to the recommendation for universal treatment of persons with HIV infection in the US, regardless of their CD4+ cell count [2, 3]. Owing to improvements in the potency and tolerability of cART and changes in US guidelines to offer treatment to all patients, HIV-infected persons in the US have been increasingly prescribed cART and achieving virologic suppression sooner after entry into HIV care [4-6]. Unfortunately, disparities in the continuum of HIV care in the US persist and access to HIV treatment and subsequent clinical responses are not equitably distributed [7-9]. For example, despite the disproportionately higher diagnosis rates of HIV infection among non-Hispanic/Latino blacks compared with non-Hispanic/Latino whites [10], men and women in the former group have had less access to and uptake of cART and higher rates of virologic non-suppression [8, 11-13]. We sought to evaluate temporal trends in cART initiation and virologic suppression in a large and demographically diverse cohort of HIV-infected patients to investigate potential risk factors and sociodemographic disparities. Understanding sociodemographic disparities is a first step toward identifying modifiable factors for interventions to improve the continuum of care for all HIV-infected persons in the US.

## METHODS

### The HIV Outpatient Study

The HIV Outpatient Study (HOPS) is an ongoing prospective observational cohort study of HIV-infected adults who have received care at nine participating HIV clinics (university-based, public and private) in six US cities (Chicago, IL; Denver, CO; Stonybrook, NY; Philadelphia, PA; Tampa, FL; and Washington, DC). The HOPS, which started in 1993, is an open cohort; patients may enter the study at any time after a diagnosis of HIV infection regardless of treatment history and may leave the study at any time for any reason (e.g., patient request, death, or loss to follow-up) [14]. Since its inception, the HOPS protocol has been reviewed and approved annually by the institutional review boards at the Centers for Disease Control and Prevention (Atlanta, GA, USA) and each of the local sites. Patient data, including sociodemographic characteristics, diagnoses, antiretroviral and other treatments, and laboratory values (including CD4+ T-lymphocyte count [CD4 cell count] and plasma HIV RNA viral load [HIV VL]) were abstracted from medical charts and entered into an electronic database for central processing and analysis.

### Study population

HOPS participants were included in this analysis if they were newly diagnosed with HIV during 2000-2013, joined the HOPS within 6 months of their diagnosis, were ART-naïve at the time of entry into HOPS, and had attended at least two clinic visits at a participating site during the study time period. Observation began at the time of HIV diagnosis and ended at the last HOPS contact, death, or 30 June 2013, whichever occurred first. We analyzed HOPS data collected during 1 January 2000 to 30 June 2013, using the HOPS dataset updated through 31 December 2013, to account for any lags in medical records abstraction.

Variable definitions

For analysis, two dates were of interest: date of first known cART use, defined per standard criteria [15, 16], and date of first virologic suppression, defined as first documented HIV VL < 500 copies/mL after HIV diagnosis. Patients were categorized according to their age at HIV diagnosis, grouped as < 25 years, 25-29 years, 30-39 years, and ≥ 40 years. Race/ethnicity was categorized as non-Hispanic/Latino white, non-Hispanic/Latino black, Hispanic/Latino, and other/unknown. Patients were further classified by whether or not they were a person who injects drugs (IDU). We classified HOPS participants hierarchically according to their HIV transmission risk as gay, bisexual, and other men who have sex with men (collectively referred to as MSM), followed by women with heterosexual contact, men with heterosexual contact, and other/unknown. Insurance payor was defined as the primary insurance provider at date of HIV diagnosis or earliest recorded payor thereafter, and was categorized as private (i.e., private insurance, preferred provider organization, health maintenance organization, point of service), public (i.e., public insurance, Medicare, Medicaid, and Ryan White/AIDS Drug Assistance Program), and other/unknown (i.e., self-pay, clinical study, other, unknown). We grouped HOPS clinic sites at which patients received care as either publicly or privately-funded institutions. We stratified year of HIV diagnosis as: 2000-2003, 2004-2007, 2008-2010, and 2011-2013. We used the laboratory values obtained closest to and within three months after HIV diagnosis to classify baseline CD4 cell count and HIV VL results. Similarly, for CD4 cell count and HIV VL at cART initiation, we analyzed the value obtained closest in time up to six months prior to the start of cART.

133 Statistical analyses

134 We calculated percentages for categorical variables and medians and interquartile ranges (IQRs)
135 for continuous variables. Subgroups of patients were compared using chi-square tests and
136 Wilcoxon rank sum tests as appropriate; ordinal categorical variables were analyzed using the
137 Cochran-Armitage test for trend.

138

139 We used Kaplan-Meier (KM) time-to-event methods and Cox proportional hazards models to
140 assess temporal trends and to identify correlates of initiating cART and of achieving viral
141 suppression after HIV diagnosis. Observation time for the primary analyses of the timing and
142 rates of cART initiation and virologic suppression began on the date of HIV diagnosis (termed
143 'index' date). In secondary analyses of rates of virologic suppression, we re-set the time origin to
144 the date of cART initiation and adjusted for laboratory values (CD4 cell count and HIV VL) at
145 the time of cART initiation. We used univariate Cox models to examine the statistical
146 association of these variables with age, race/ethnicity, IDU, HIV risk group (composite variable
147 of HIV risk and sex with subgroups: MSM, heterosexual women, heterosexual men and
148 other/unknown risk), primary insurance payor, type of institution, period of HIV diagnosis, and
149 baseline CD4 cell count. We constructed multivariable Cox models that included all variables
150 from the univariate analyses, regardless of their statistical significance, in order to facilitate
151 comparison of model findings for cART initiation and virologic suppression and to control for
152 residual confounding. Results from the Cox proportional hazards models are reported as hazard
153 ratios (HR) with associated 95% confidence intervals (CI). P-values less than 0.05 were
154 considered statistically significant. All analyses were performed using SAS version 9.3 (SAS
155 Institute, Cary, NC).

156

157 RESULTS

158 The 1,156 HOPS patients who met eligibility criteria had a median age of 37.0 years (IQR: 29.1-
159 45.4), 74.8% were male, and the study sample was ethnically diverse: 39.0% were non-
160 Hispanic/Latino white, 43.2% non-Hispanic/Latino black, 14.1% Hispanic/Latino and
161 race/ethnicity was other/unknown for 3.7%; 52.4% of patients were MSM and 51.7% were
162 privately insured (Table 1).

163

164 CD4 cell count at HIV diagnosis

165 The median CD4 cell count at HIV diagnosis was somewhat higher in consecutive time periods
166 in the study: 284 cells/mm$^3$ in 2000-2003 compared with 337 cells/mm$^3$ in 2011-2013 (test for
167 trend $p = 0.064$, not significantly significant). The median CD4 cell count at HIV diagnosis
168 varied markedly among patient subgroups: 177 cells/mm$^3$ for heterosexual men, 371 cells/mm$^3$
169 for MSM, and 314 cells/mm$^3$ for heterosexual women ($p < 0.01$). Non-Hispanic/Latino blacks
170 and Hispanics/Latinos were diagnosed with lower CD4 cell counts than whites: median 285
171 cells/mm$^3$ for non-Hispanic/Latino blacks, 225 cells/mm$^3$ for Hispanic/Latinos, and 374
172 cells/mm$^3$ for non-Hispanic/Latino whites ($p < 0.01$).

173

174 CD4 cell count at cART initiation

175 The median CD4 cell count at cART initiation was higher for patients *diagnosed in consecutive*
176 *time periods of the study*: 207 cells/mm$^3$ in 2000-2003, 231 cells/mm$^3$ in 2004-2007, 317
177 cells/mm$^3$ in 2008-2010, and 317 cells/mm$^3$ in 2011-2013 (test for trend $p < 0.001$). Similarly,
178 for the subset of patients *observed to start cART* in a given calendar interval, the median CD4

cell count at cART initiation was 196 cells/$mm^3$ in 2000-2003 (n = 278), 222 cells/$mm^3$ in 2004-2007 (n = 308), 317 cells/$mm^3$ in 2008-2010 9 (n = 225), and 321 cells/$mm^3$ in 2011-2013 (n = 115) (test for trend $p < 0.001$). MSM and heterosexual women had higher CD4 cell counts at cART initiation than did heterosexual men ($p < 0.001$; data not shown); additionally, patients of non-Hispanic/Latino white race/ethnicity had higher CD4 cell counts than those of non-Hispanic black and Hispanic/Latino race/ethnicity ($p < 0.001$; data not shown). There were no statistically significant differences by IDU group for CD4 cell count at cART initiation.

Time to cART Initiation after HIV diagnosis

Overall, 926 (80.1%) of eligible patients began cART during the study period. Compared with patients who did not, patients who started cART were older (median age 37.7 vs. 34.8 years), more frequently of non-Hispanic/Latino white race/ethnicity (41.0% vs. 30.9%), and less frequently IDU participants (3.8% vs. 8.7%). They were also more likely to have been diagnosed with AIDS at the time of their HIV diagnosis (20.8% vs. 6.1%), and to have a lower CD4 cell count (median 271 vs. 517 cells/$mm^3$) and higher HIV VL (median 4.8 vs. 4.2 $\log_{10}$ copies/mL) (Table 1; $p < 0.05$ for all). Patients who did vs. did not start cART during the study period did not differ significantly in terms of sex, HIV transmission risk group, insurance payor, institution, or calendar period of HIV diagnosis.

In univariate analyses, the estimated median duration from HIV diagnosis to cART initiation was progressively shorter for persons diagnosed with HIV in later calendar periods: the median time was 4.4 months for persons diagnosed in 2000-2003 and 2.5 months for persons diagnosed in 2011-2013 (log rank test $p < 0.001$, Figure 1A). In univariate Cox proportional hazards models

for 2000-2013, factors significantly ($p < 0.05$) associated with *later* cART initiation included age < 25 years (compared to ≥40 years) and IDU (Table 2). However, factors significantly associated with *earlier* cART initiation included being a heterosexual man or belonging to other/unknown risk group (compared with MSM), being diagnosed with HIV infection in later calendar periods, and having a lower CD4 cell count at diagnosis (Table 2). After adjusting for CD4 cell count and all other variables displayed in Table 2, later cART initiation was now significant for persons of non-Hispanic/Latino black race/ethnicity (adjusted hazard ratio [aHR] 0.8, 95% CI 0.7-0.9, as compared with non-Hispanic/Latino white; Figure 2A shows unadjusted curves) and IDUs (aHR 0.6, 95% CI 0.4-0.8, vs. non-IDU). Compared with the period 2000-2003, the likelihood of initiating cART after diagnosis increased significantly for persons HIV diagnosed during 2004-2007 (aHR 1.3, 95% CI 1.1-1.5), during 2008-2010 (aHR 1.4, 95% CI 1.2-1.7), and during 2011-2013 (aHR 2.0, 95% CI 1.6-2.6). Compared with patients whose CD4 cell count at HIV diagnosis was at least 350 cells/$mm^3$, those diagnosed with CD4 cell count less than 200 cells/$mm^3$ (aHR 5.0, 95% CI 4.1-5.9) or CD4 cell count 200-349 cells/$mm^3$ (aHR 2.2, 95% CI 1.8-2.7) were more likely to initiate cART more promptly after HIV diagnosis.

Achieving virologic suppression after HIV diagnosis

Of the 1,156 patients included in this analysis, 916 (79.2%) achieved virologic suppression during the study period. In univariate analyses, the median time to virologic suppression improved for those diagnosed with HIV infection in later calendar periods: it was 10.2 months for patients diagnosed in 2000-2003 and 5.4 months for patients diagnosed in 2011-2013 (log rank test $p < 0.001$, Figure 1B). In univariate Cox proportional hazards models for 2000-2013, factors significantly ($p < 0.05$) associated with later virologic suppression were age < 25 years

and age 25-29 years (compared with ≥ 40 years), non-Hispanic/Latino black race/ethnicity (compared with Hispanic/Latino white), and receiving care at a publicly-funded institution (compared with private institutions), whereas having a HIV diagnosis in later calendar years and having lower CD4 cell count at diagnosis were associated with shorter time to virologic suppression. In multivariable analyses, adjusting for CD4 cell count and all other variables displayed in Table 2, the factors independently associated with later virologic suppression were age < 25 years (aHR 0.8, 95% CI 0.6-1.0) and age 25-29 years (aHR 0.8, 95%CI 0.6-1.0) compared with ≥40 years, non-Hispanic/Latino black race/ethnicity (aHR 0.8, 95% CI 0.7-1.0, as compared with Hispanic/Latino white), and receiving care at a publicly-funded institution (aHR 0.8, 95% CI 0.7-1.0). Compared with participants diagnosed in the period 2000-2003, those diagnosed in 2004-2007 (aHR 1.3, 95% CI 1.1-1.6), 2008-2010 (aHR 2.0, 95% CI 1.7-2.4), or 2011-2013 (aHR 2.6, 95% CI 2.0-3.4) achieved VL suppression more rapidly. Compared with patients diagnosed with HIV with CD4 cell count at least 350 cells/$mm^3$, those with CD4 cell count less than 200 cells/$mm^3$ (aHR 1.9, 95% CI 1.6-2.2) or CD4 cell count 200-349 cells/$mm^3$ (aHR 1.7, 95% CI 1.4-2.0) were more likely to have a shorter time to virologic suppression.

Achieving virologic suppression after cART initiation

We performed a secondary analysis by resetting the time origin in Cox regression analyses to the date of cART initiation (instead of the date of HIV diagnosis) to assess disparities in virologic suppression among those patients who were prescribed cART. Of the 1,156 patients included in our main analysis, 926 began cART; 835 of whom subsequently achieved virologic suppression during study observation.

In univariate analyses, in addition to the disparities noted in Table 2 regarding time to achieving virologic suppression by age, race/ethnicity, institution, and period of HIV diagnosis (see also Figures 1B and 2B), we observed additional disparities by HIV risk group and insurance payor, whereas age was no longer significant (Table 3). In multivariable analyses, participants age < 25 years were less likely to achieve virologic suppression (aHR 0.7, 95% CI 0.6-0.9) and those age 25-29 (aHR 0.8, 95% CI 0.6-1.0) when compared with those age ≥ 40 years, and non-Hispanic/Latino blacks were less likely to achieve virologic suppression than non-Hispanic/Latino whites (aHR 0.8, 95% CI 0.7-1.0). The likelihood of achieving earlier virologic suppression improved over time: compared with patients diagnosed during 2000-2003, the adjusted HR was higher for patients diagnosed in 2004-2007 (aHR 1.2, 95% CI 1.0-1.4), 2008-2010 (aHR 1.2, 95% CI 1.0-1.5) and 2011-2013 (aHR 1.8, 95% CI 1.4-2.3). Patients with HIV VL ≥ 5 $\log_{10}$ copies/mL took longer to achieve virologic suppression after cART initiation (aHR 0.7, 95% CI 0.6-0.8), compared with those having HIV VL from 3-5 $\log_{10}$ copies/mL. Neither IDU nor CD4 cell count at cART initiation were independently associated with time to virologic suppression after cART initiation.

## DISCUSSION

In this longitudinal, observational cohort of HIV-infected U.S. patients, time to initiation of cART and time to virologic suppression have improved markedly during 2000-2013 for patients who entered HIV care within six months after their diagnosis. Our results are similar to earlier findings from a large North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD) [6], and somewhat exceed the estimates from the National HIV Surveillance System, which reported that among persons diagnosed with HIV infection in 2009 who entered care

within the next three months, the median time from HIV diagnosis to viral suppression was approximately 11 months [4].

In the present report, and in an earlier HOPS analysis through year 2009 [16], there were no statistically significant improvements over the years in CD4 cell counts at time of HIV diagnosis. However, in the current analysis, we found a significant increase in CD4 counts at the time of cART initiation. From the vantage point of our analysis cohort, which includes only persons who successfully linked to HIV care at HOPS clinics, once patients were diagnosed and in HIV care, they initiated therapy increasingly more promptly, a finding consistent with changes in treatment guidelines recommending that treatment be offered to all patients regardless of CD4 cell count [2]. As a result of earlier cART initiation and likely improvements in potency and tolerability of cART over time, we observed more prompt virologic suppression after HIV diagnosis across the study intervals.

Despite overall improvements, we found that some patient subgroups lagged behind others in initiating cART and achieving virologic suppression, as has been shown in other populations [5, 7, 12]. Most notably, non-Hispanic/Latino blacks experienced delays in initiating cART as compared with non-Hispanic/Latino whites even after controlling for public insurance payor (a surrogate indicator of poverty) and being enrolled at publicly funded sites; both variables have been shown to be associated with poorer outcomes in the HOPS cohort [15, 16]. The association of non-Hispanic/Latino black race with later initiation of cART may stem from residual confounding by poverty, access to HIV care, or other structural or psychosocial factors that were not captured by our medical abstraction study [6]. Other studies addressing racial disparities in

cART initiation or discontinuation identified stigma, fear of disclosure [17], distrust of the medical establishment or providers [18-23], low literacy [24], poor access to case management [25], and racial/ethnic discrimination [26, 27] as contributing factors. Other factors associated with poverty, including living in high-crime neighborhoods and substance abuse, may also contribute to delayed access to effective care[28]. The health impact of incarceration and subsequent barriers to re-entry into society are difficult to measure but also likely affect access to HIV care [29].

Heterosexual women were diagnosed with HIV at lower CD4 cell counts than MSM, but did not experience delays in initiating cART and did not lag behind MSM in time to virologic suppression, in contrast to findings by others [1, 21]. Of note, HIV among heterosexual men had significantly lower median CD4 counts at diagnosis compared with other risk groups, but once diagnosed, they initiated cART and achieved virologic suppression no later than MSM (Table 2). Later diagnosis among heterosexual men vs. MSM echoes findings from some European countries, which differ demographically from the US [30, 31]. A recent study from Florida also observed that heterosexual men were being diagnosed late (i.e., at lower CD4 cell counts) in rural compared with urban settings [32]. Unlike the Florida study, the HOPS cohort is based in urban US settings. Heterosexual men may not perceive themselves at risk for HIV infection, and therefore may not seek HIV testing, but just as heterosexual.women are at risk, their heterosexual male counterparts are no less so.

Perhaps the most important finding from the current analysis was the age-related disparities, with patients age < 25 years at HIV diagnosis or cART initiation and marked delays in achieving

317 virologic suppression compared with patients age ≥ 40 years, even after adjusting for CD4 cell
318 counts and calendar year of HIV diagnosis. The incidence rate of new HIV infections has been
319 increasing most rapidly among young adults, which is also the group with the greatest delays in
320 accessing HIV care and poorest adherence to ART and virologic suppression [33-36]. Among the
321 estimated 47,500 new HIV infections in the US in 2010, about 29,800 (or 63%) occurred among
322 MSM, of whom about 36% were non-Hispanic/Latino black and 30% were 13-24 years old [33].
323 Nonadherence to treatment among youth is not unique to HIV, and has been reported with other
324 chronic illnesses [37]. Youth with HIV have poorer access to care, adherence to medication, and
325 retention in care than adults (reviewed in Zanoni and Mayer, 2003 [38]).
326
327 Our study has some limitations. We studied patients who were linked to HIV care and enrolled in
328 the HOPS study within six months of their HIV diagnosis, thus our findings may reflect more
329 favorable patterns in cART initiation and viral suppression than would be observed for all HIV-
330 infected patients in the US, an estimated 23% of whom do not promptly enter HIV care after
331 being diagnosed [39]. We relied on routinely abstracted medical records data and did not capture
332 information on some potential structural and psychosocial confounders, as noted above.
333 Measurements of HIV viral load were conducted as part of routine HIV care, and because the
334 schedule of viral load monitoring may vary by physician practice and individual patient's
335 adherence to clinical visits [40], we may have overestimated the median times to virologic
336 suppression. The delay to virologic suppression after controlling for time to cART start could
337 well reflect poor adherence to prescribed cART, which we did not have data to evaluate in this
338 study. Failure to suppress HIV VL highly correlates with non-adherence [41]. Finally, we did
339 not have available data on some patient-level risk factors for delayed cART start or adherence to

care and cART, such as depression, alcohol dependence, nor structural and socioeconomic factors as income, housing instability or stigma and discrimination, that could interfere with achieving optimal outcomes [17, 19, 42].

In conclusion, we found that over a 13.5-year period (2000-2013), while the CD4 count at HIV diagnosis has not improved significantly among enrollees in the HOPS, the timeliness of initiation of cART and subsequent virologic suppression have both improved. However, heterosexual men were diagnosed at significantly lower CD4 counts than all other subgroups. Non-Hispanic/Latino blacks initiated treatment and achieved virologic suppression significantly later than all other subgroups. Young people age < 25 years also experienced significantly later virologic suppression compared with persons age ≥ 40 years. These observations highlight the disparities that persist within the US continuum of HIV care that must be adequately addressed as part of the National HIV/AIDS strategy[1, 8].

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Appendix 1: HIV Outpatient Study Investigators

**The HIV Outpatient Study (HOPS) Investigators include the following persons and sites**:

John T. Brooks, Kate Buchacz, and Marcus D. Durham, Division of HIV/AIDS Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC), Atlanta, GA; Kathleen C. Wood, Darlene Hankerson, Rachel Hart, Harlen Hays, Jeffrey Binkley, Carl Armon, Thilakavathy Subramanian, Dana Franklin, and Bonnie Dean, Cerner Corporation, Vienna, VA; Frank J. Palella, Joan S. Chmiel, Conor Flaherty, and Saira Jahingar, Feinberg School of Medicine, Northwestern University, Chicago, IL; Kenneth A. Lichtenstein and Cheryl Stewart, National Jewish Medical and Research Center, Denver, CO; John Hammer, Kenneth S. Greenberg, Barbara Widick, and Rosa Franklin, Rose Medical Center, Denver, CO; Bienvenido G. Yangco and Kalliope Halkias, Infectious Disease Research Institute, Tampa, FL; Doug Ward and Troy Thomas, Dupont Circle Physicians Group, Washington, DC; Jack Fuhrer, Linda Ording-Bauer, Rita Kelly, and Jane Esteves, State University of New York (SUNY), Stonybrook, NY; Ellen M. Tedaldi, Ramona A. Christian, Faye Ruley, Dania Beadle, and Princess Graham, Temple University School of Medicine, Philadelphia, PA; Richard M. Novak, Andrea Wendrow, and Renata Smith, University of Illinois at Chicago, Chicago, IL; Benjamin Young and Barbara Widick, APEX Family Medicine, Denver, CO.

Table 1. Characteristics of HIV-infected patients overall and stratified by whether or not patients began cART, the HIV Outpatient Study, 2000–2013.

| | Total<br><br>N = 1,156 | Began cART<br><br>N = 926 | Did not begin cART<br><br>N = 230 | % of total who began cART (80.1%) | P-value[3] |
|---|---|---|---|---|---|
| Age at index date (years)[1], n (%) | | | | | 0.001 |
| < 25 | 148 (12.8) | 105 (11.3) | 43 (18.7) | 70.9 | |
| 25-29 | 168 (14.5) | 130 (14.0) | 38 (16.5) | 77.4 | |
| 30-39 | 381 (33.0) | 307 (33.2) | 74 (32.2) | 80.6 | |
| 40+ | 459 (39.7) | 384 (41.5) | 75 (32.6) | 83.7 | |
| Median age (IQR) | 37.0 (29.1, 45.4) | 37.7 (29.8, 45.7) | 34.8 (27.0, 43.2) | | 0.003 |
| Sex, n (%) | | | | | 0.39 |
| Female | 291 (25.2) | 228 (24.6) | 63 (27.4) | 78.4 | |

| | | | | | |
|---|---|---|---|---|---|
| Male | 865 (74.8) | 698 (75.4) | 167 (72.6) | 80.7 | |
| Race/ethnicity, n (%) | | | | | 0.026 |
| Non-Hispanic/Latino white | 451 (39.0) | 380 (41.0) | 71 (30.9) | 84.3 | |
| Non-Hispanic/Latino black | 499 (43.2) | 383 (41.4) | 116 (50.4) | 76.8 | |
| Hispanic/Latino | 163 (14.1) | 131 (14.1) | 32 (13.9) | 80.4 | |
| Other/Unknown | 43 (3.7) | 32 (3.5) | 11 (4.8) | 74.4 | |
| IDU, n (%) | | | | | 0.002 |
| Yes | 55 (4.8) | 35 (3.8) | 20 (8.7) | 63.6 | |
| No | 1,101 (95.2) | 891 (96.2) | 210 (91.3) | 80.9 | |
| HIV Risk Group, n (%) | | | | | 0.11 |
| MSM | 606 (52.4) | 488 (52.7) | 118 (51.3) | 80.5 | |
| Heterosexual Women | 265 (22.9) | 204 (22.0) | 61 (26.5) | 77.0 | |
| Heterosexual Men | 202 (17.5) | 160 (17.3) | 42 (18.3) | 79.2 | |
| Other/Unknown | 83 (7.2) | 74 (8.0) | 9 (3.9) | 89.2 | |
| Insurance Payor, n (%) | | | | | 0.10 |
| Private | 598 (51.7) | 491 (53.0) | 107 (46.5) | 82.1 | |

| | | | | | |
|---|---|---|---|---|---|
| Public | 393 (34.0) | 301 (32.5) | 92 (40.0) | 76.6 | |
| Other/Unknown | 165 (14.3) | 134 (14.5) | 31 (13.5) | 81.2 | |
| Institution, n (%) | | | | | 0.055 |
| Private | 604 (52.2) | 497 (53.7) | 107 (46.5) | 82.3 | |
| Public | 552 (47.8) | 429 (46.3) | 123 (53.5) | 77.7 | |
| Period of index date[1], n (%) | | | | | 0.76 |
| 2000-2003 | 445 (38.5) | 342 (36.9) | 103 (44.8) | 76.9 | |
| 2004-2007 | 362 (31.3) | 306 (33.1) | 56 (24.3) | 84.5 | |
| 2008-2010 | 225 (19.5) | 185 (20.0) | 40 (17.4) | 82.2 | |
| 2011-2013 | 124 (10.7) | 93 (10.0) | 31 (13.5) | 75.0 | |
| Days from index date[1] to HOPS entry, median (IQR) | 25 (10.5, 50) | 23.5 (10, 48) | 30 (12, 62) | | 0.005 |
| AIDS defined at index[1], n (%) | | | | | < .001 |
| Yes | 207 (17.9) | 193 (20.8) | 14 (6.1) | 93.2 | |
| No | 949 (82.1) | 733 (79.2) | 216 (93.9) | 77.2 | |
| Nadir CD4 at start of cART | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| (cells/mm$^3$)$^2$, n (%) | | | | | |
| < 50 | | 162 (17.5) | NA | | |
| 50-99 | | 74 (8.0) | NA | | |
| 100-199 | | 140 (15.1) | NA | | |
| 200-349 | | 246 (26.6) | NA | | |
| ≥ 350 | | 235 (25.4) | NA | | |
| Unknown | | 69 (7.4) | NA | | |
| Median nadir CD4 (cells/mm$^3$)$^2$ | | 233 (85, 360) | NA | | |
| (IQR) | | | | | |
| CD4 count at index date | | | | | < .001 |
| (cells/mm$^3$)$^2$, n (%) | | | | | |
| < 200 | 337 (29.2) | 314 (33.9) | 23 (10.0) | 93.2 | |
| 200-349 | 204 (17.6) | 174 (18.8) | 30 (13.0) | 85.3 | |
| ≥ 350 | 434 (37.5) | 302 (32.6) | 132 (57.4) | 69.6 | |
| Unknown | 181 (15.7) | 136 (14.7) | 45 (19.6) | 75.1 | |
| Median CD4 count (cells/mm$^3$)$^2$ | 309 (115, 517) | 271 (97, 456) | 517 (317, 780) | | < .001 |

| | | | | | |
|---|---|---|---|---|---|
| (IQR) | | | | | |
| Viral load at index date ($log_{10}$ copies/mL)[2], n (%) | | | | | < .001 |
| Undetectable | 28 (2.4) | 8 (0.9) | 20 (8.7) | 28.6 | |
| < 3 (but detectable) | 46 (4.0) | 27 (2.9) | 19 (8.3) | 58.7 | |
| ≥ 3 and < 5 | 536 (46.4) | 430 (46.4) | 106 (46.1) | 80.2 | |
| ≥ 5 | 358 (31.0) | 318 (34.3) | 40 (17.4) | 88.8 | |
| Unknown | 188 (16.3) | 143 (15.4) | 45 (19.6) | 76.1 | |
| Median viral load ($log_{10}$ copies/mL)[2], (IQR) | 4.7 (4.1, 5.3) | 4.8 (4.3, 5.3) | 4.2 (3.1, 4.9) | | < .001 |

[1] Index date is date of HIV diagnosis.

[2] Closest date from values documented 6 months prior to 3 months after date.

[3] P-values for differences in distributions (comparing patients who began cART versus those who did not) for categorical variables are based on a chi-squared test; p-values for comparing medians are based on a 2-sided Wilcoxon rank sum test; p-values for ordinal variables are obtained from a Cochran-Armitage test for trend.

Abbreviations: AIDS, acquired immunodeficiency syndrome; cART, combination antiretroviral therapy; IDU, persons who inject drugs; IQR, interquartile range; MSM, men who have sex with men; NA, not applicable.

Table 2. Factors associated with time to initiation of cART and time to virologic suppression, the HIV Outpatient Study, 2000 – 2013 (N=1,156).

| | Time to Initiation of cART[1] | | | | Time to Virologic Suppression[1] | | | |
|---|---|---|---|---|---|---|---|---|
| | Univariate | | Multivariable[2] | | Univariate | | Multivariable[2] | |
| | HR (95% CI) | P-value | aHR (95% CI) | P-value | HR (95% CI) | P-value | aHR (95% CI) | P-value |
| Age (years) | | | | | | | | |
| < 25 | 0.7 (0.6, 0.9) | 0.008 | 0.9 (0.7, 1.1) | 0.16 | 0.7 (0.6, 0.9) | 0.003 | 0.8 (0.6, 1.0) | 0.037 |
| 25-29 | 0.8 (0.7, 1.0) | 0.08 | 0.9 (0.7, 1.1) | 0.34 | 0.8 (0.6, 0.9) | 0.007 | 0.8 (0.6, 1.0) | 0.031 |
| 30 - 39 | 0.9 (0.8, 1.0) | 0.17 | 0.9 (0.8, 1.1) | 0.26 | 0.9 (0.8, 1.0) | 0.08 | 0.9 (0.8, 1.1) | 0.19 |
| ≥ 40 | Referent | | Referent | | Referent | | Referent | |
| Race/ethnicity | | | | | | | | |
| Non-Hispanic/Latino white | Referent | | Referent | | Referent | | Referent | |
| Non-Hispanic/Latino black | 0.9 (0.8,1.0) | 0.14 | 0.8 (0.7, 0.9) | 0.008 | 0.8 (0.7, 1.0) | 0.022 | 0.8 (0.7, 1.0) | 0.035 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Hispanic/Latino | 1.1 (0.9,1.4) | 0.31 | 0.9 (0.7, 1.1) | 0.38 | 1.0 (0.9, 1.3) | 0.44 | 1.1 (0.8, 1.3) | 0.59 |
| Other/Unknown | 0.9 (0.6,1.3) | 0.68 | 1.0 (0.7, 1.4) | 0.79 | 1.0 (0.8, 1.5) | 0.67 | 1.1 (0.8, 1.6) | 0.46 |
| IDU | | | | | | | | |
| Yes | 0.6 (0.4, 0.8) | 0.004 | 0.6 (0.4, 0.8) | 0.002 | 0.8 (0.5, 1.0) | 0.09 | 0.8 (0.6, 1.1) | 0.20 |
| No | Referent | | Referent | | Referent | | Referent | |
| HIV Risk Group | | | | | | | | |
| MSM | Referent | | Referent | | Referent | | Referent | |
| Heterosexual Women | 0.9 (0.8, 1.1) | 0.38 | 1.0 (0.8, 1.2) | 0.69 | 1.0 (0.8, 1.1) | 0.68 | 1.2 (1.0, 1.5) | 0.06 |
| Heterosexual Men | 1.3 (1.1, 1.5) | 0.007 | 1.1 (0.9, 1.4) | 0.23 | 1.1 (0.9, 1.4) | 0.17 | 1.2 (0.9, 1.5) | 0.17 |
| Other/Unknown | 1.3 (1.1, 1.7) | 0.018 | 1.2 (0.9, 1.6) | 0.13 | 1.1 (0.8, 1.4) | 0.55 | 1.2 (0.9, 1.5) | 0.32 |
| Insurance Payor | | | | | | | | |
| Private | Referent | | Referent | | Referent | | Referent | |
| Public | 1.1 (0.9, 1.2) | 0.36 | 1.0 (0.8, 1.2) | 0.71 | 1.0 (0.9, 1.1) | 0.88 | 1.0 (0.8, 1.2) | 0.72 |
| Other/Unknown | 1.1 (0.9, 1.3) | 0.27 | 1.0 (0.8, 1.2) | 0.80 | 0.9 (0.8, 1.2) | 0.61 | 0.9 (0.7, 1.1) | 0.31 |
| Institution | | | | | | | | |
| Private | Referent | | Referent | | Referent | | Referent | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Public | 0.9 (0.8, 1.1) | 0.22 | 0.9 (0.8, 1.1) | 0.30 | 0.9 (0.8, 1.0) | 0.025 | 0.8 (0.7, 1.0) | 0.033 |
| Period of index date[3] | | | | | | | | |
| 2000 - 2003 | Referent | | Referent | | Referent | | Referent | |
| 2004 - 2007 | 1.2 (1.0, 1.4) | 0.052 | 1.3 (1.1, 1.5) | 0.002 | 1.3 (1.1, 1.5) | 0.004 | 1.3 (1.1, 1.6) | <.001 |
| 2008 - 2010 | 1.2 (1.0, 1.5) | 0.019 | 1.4 (1.2, 1.7) | <.001 | 1.8 (1.5, 2.1) | <.001 | 2.0 (1.7, 2.4) | <.001 |
| 2011 - 2013 | 1.6 (1.3, 2.0) | <.001 | 2.0 (1.6, 2.6) | <.001 | 2.1 (1.6, 2.7) | <.001 | 2.6 (2.0, 3.4) | <.001 |
| CD4 count at index date (cells/mm$^3$)[3] | | | | | | | | |
| < 200 | 4.6 (3.9, 5.5) | <.001 | 5.0 (4.1, 5.9) | <.001 | 1.7 (1.5, 2.0) | <.001 | 1.9 (1.6, 2.2) | <.001 |
| 200 - 349 | 2.1 (1.7, 2.5) | <.001 | 2.2 (1.8, 2.7) | <.001 | 1.5 (1.3, 1.9) | <.001 | 1.7 (1.4, 2.0) | <.001 |
| ≥ 350 | Referent | | Referent | | Referent | | Referent | |
| Unknown | 1.1 (0.9,1.3) | 0.60 | 1.1 (0.9, 1.4) | 0.25 | 0.8 (0.6, 1.0) | 0.022 | 0.8 (0.7, 1.0) | 0.06 |

[1] Hazard ratios greater than 1 indicate earlier initiation of cART or earlier virologic suppression.

[2] All variables from the univariate models are included in the multivariable model.

[3] Index date is the date of HIV diagnosis.

Abbreviations: aHR, adjusted hazard ratio; cART, combination antiretroviral therapy; CI, confidence interval; HR, hazard ratio; IDU, persons who inject drugs; MSM, men who have sex with men.

Table 3. Factors associated with time to virologic suppression after cART initiation, the HIV Outpatient Study, 2000 – 2013 (N=926).

| | Time to Virologic Suppression[1] | | | |
|---|---|---|---|---|
| | Univariate | | Multivariable[2] | |
| | HR (95% CI) | P-value | aHR (95% CI) | P-value |
| Age (years) | | | | |
| < 25 | 0.8 (0.6, 1.0) | 0.09 | 0.7 (0.6, 0.9) | 0.009 |
| 25 - 29 | 0.8 (0.7, 1.1) | 0.13 | 0.8 (0.6, 1.0) | 0.047 |
| 30 - 39 | 0.9 (0.8, 1.1) | 0.28 | 0.9 (0.8, 1.0) | 0.14 |
| ≥ 40 | Referent | | Referent | |
| Race/ethnicity | | | | |
| Non-Hispanic/Latino white | Referent | | Referent | |
| Non-Hispanic/Latino black | 0.8 (0.7, 0.9) | 0.001 | 0.8 (0.7, 1.0) | 0.048 |
| Hispanic/Latino | 0.8 (0.7, 1.0) | 0.072 | 0.9 (0.7, 1.1) | 0.38 |
| Other/Unknown | 0.9 (0.6, 1.3) | 0.58 | 0.8 (0.6, 1.2) | 0.40 |
| IDU | | | | |
| Yes | 1.0 (0.7, 1.4) | 0.88 | 1.0 (0.7, 1.5) | 0.88 |
| No | Referent | | Referent | |
| HIV Risk Group | | | | |

| | | | | |
|---|---|---|---|---|
| MSM | Referent | | Referent | |
| Heterosexual Women | 0.8 (0.7, 1.0) | 0.023 | 1.0 (0.8, 1.2) | 0.90 |
| Heterosexual Men | 0.9 (0.7, 1.1) | 0.30 | 1.1 (0.8, 1.3) | 0.67 |
| Other/Unknown | 0.9 (0.7, 1.2) | 0.37 | 1.0 (0.8, 1.4) | 0.81 |
| Insurance Payor | | | | |
| Private | Referent | | Referent | |
| Public | 0.8 (0.7, 1.0) | 0.035 | 0.9 (0.8, 1.1) | 0.36 |
| Other/Unknown | 0.9 (0.7, 1.1) | 0.41 | 1.0 (0.8, 1.3) | 0.73 |
| Institution | | | | |
| Private | Referent | | Referent | |
| Public | 0.8 (0.7, 0.9) | 0.004 | 0.9 (0.8, 1.1) | 0.26 |
| Period of index date[3] | | | | |
| 2000 - 2003 | Referent | | Referent | |
| 2004 - 2007 | 1.2 (1.1, 1.5) | 0.010 | 1.2 (1.0, 1.4) | 0.021 |
| 2008 - 2010 | 1.3 (1.1, 1.6) | 0.002 | 1.2 (1.0, 1.5) | 0.046 |
| 2011 - 2013 | 1.7 (1.3, 2.2) | <.001 | 1.8 (1.4, 2.3) | <.001 |
| CD4 at cART initiation (cells/$mm^3$)[4] | | | | |
| <200 | 0.7 (0.6, 0.9) | <.001 | 0.9 (0.7, 1.0) | 0.14 |
| 200-349 | 1.1 (0.9, 1.3) | 0.25 | 1.2 (1.0, 1.5) | 0.07 |
| ≥ 350 | Referent | | Referent | |
| Unknown | 0.6 (0.5, 0.8) | <.001 | 0.8 (0.6, 1.2) | 0.29 |

| | | | | |
|---|---|---|---|---|
| Log VL at cART initiation ($log_{10}$ copies/mL)[4] | | | | |
| < 3 | 1.1 (0.7, 1.6) | 0.77 | 1.3 (0.8, 2.0) | 0.28 |
| ≥ 3 and < 5 | Referent | | Referent | |
| ≥ 5 | 0.7 (0.6, 0.8) | <.001 | 0.7 (0.6, 0.8) | <.001 |
| Unknown | 0.5 (0.4, 0.7) | <.001 | 0.6 (0.5, 0.8) | 0.001 |

[1] Hazard ratios greater than 1 indicate earlier initiation of cART or earlier virologic suppression; based on Cox proportional hazards models

[2] All variables from the univariate models are included in the multivariable model.

[3] Index date is the date of HIV diagnosis.

[4] Closest lab value to cART initiation up to 6 months prior.

Abbreviations: aHR, adjusted hazard ratio; cART, combination antiretroviral therapy; CI, confidence interval; HR, hazard ratio; IDU, persons who inject drugs; MSM, men who have sex with men; VL, viral load

Figure 1A. Time from HIV diagnosis to 1st use of cART by period of HIV diagnosis, the HIV Outpatient Study, 2000-2013 (N=1,156)

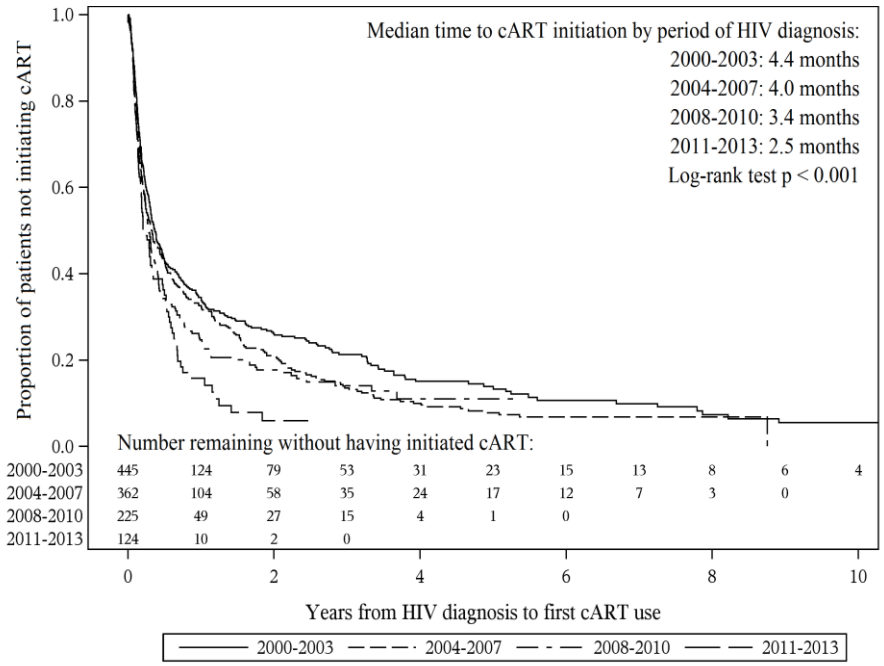


Figure 1B. Time from HIV diagnosis to virologic suppression by period of HIV diagnosis, the HIV Outpatient Study, 2000-2013 (N=1,156).

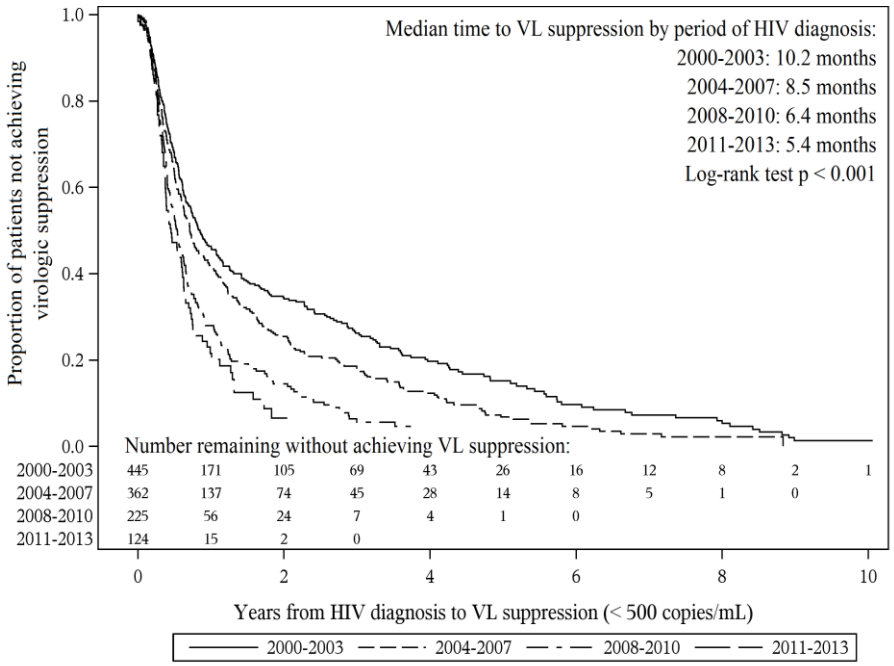

Figure 2A. Time from HIV diagnosis to 1st use of cART by race/ethnicity, the HIV Outpatient Study, 2000-2013 (N=1,156).

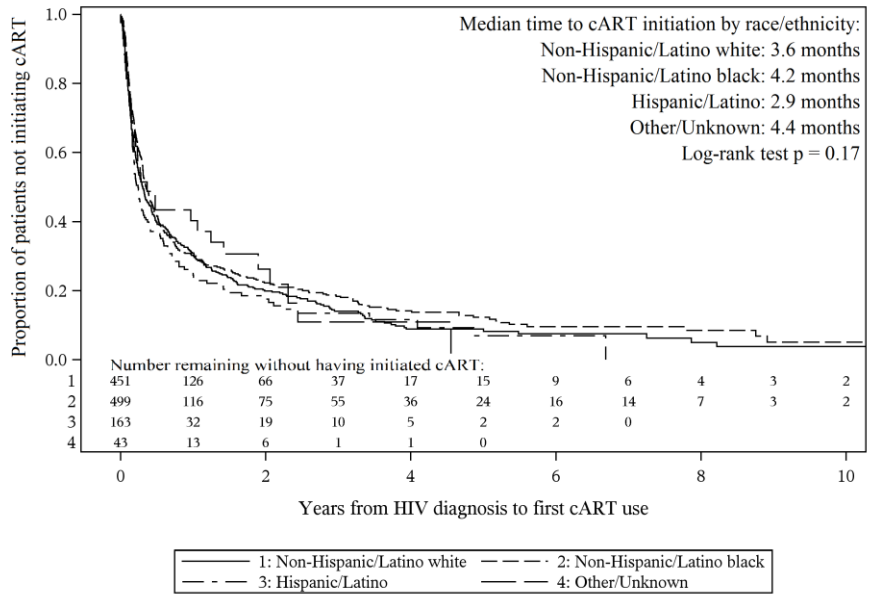


Figure 2B. Time from HIV diagnosis to virologic suppression by race/ethnicity, the HIV Outpatient Study, 2000-2013 (N=1,156).